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IN THE FIRST JUDICIAL DISTRICT COURT, LEWIS AND CLARK COUNTY

THE STATE OF MONTANA *ex rel*., MIKE McGRATH, Attorney General,

Plaintiff,

v.

ABBOTT LABORATORIES, INC.; AMERICAN HOME PRODUCTS CORPORATION; AMGEN INC.; ASTRAZENECA; AVENTIS PHARMA; CHIRON; BAXTER PHARMACEUTICAL PRODUCTS, INC.; BRISTOL-MYERS SQUIBB COMPANY; DEY, INC.; SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE CORPORATION; PHARMACIA CORPORATION; HOECHST MARION ROUSSEL, INC.; IMMUNEX CORPORATION; ELI LILLY AND COMPANY; SCHERING-PLOUGH CORP.; PHARMACIA & UPJOHN COMPANY; SMITHKLINE BEECHAM CORPORATION; WARRICK PHARMACEUTICALS CORPORATION and DOES 1-100; DOES 101-125; DOES 126-150 and DOES 151-200,

Defendants.

Cause No.: _____

COMPLAINT FOR INJUNCTIVE RELIEF, DAMAGES, RESTITUTION, DISGORGEMENT, PENALTIES AND OTHER RELIEF AND DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. The State of Montana, through Attorney General Mike McGrath, brings this action for monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits and punitive damages on behalf of the State of Montana, and restitution on behalf of persons in Montana including thousands of Patients[1] who have paid inflated charges for medications based in whole or in part on Defendants' use of the Average Wholesale Price ("AWP") Scheme, as described below.

2. Each of the Defendants is or has been engaged in the business of manufacturing, marketing and selling prescription pharmaceuticals throughout the United States. The principal payors for such prescription pharmaceuticals are federal and/or state governments (under, respectively, the Medicare and Medicaid Programs), private insurers and self-insured employers (Third-Party Payors), and private individuals (Patients), including elderly patients who make payments for drugs under the Medicare program.

3. Prescription drugs are an increasingly important part of life for most Montana citizens. The development of new drugs can benefit consumers through better overall health, avoidance of more expensive surgical procedures, and, in some cases, longer life. Because for many people, prescription drugs are necessary to live or function normally, consumers often have no choice but to pay whatever price is necessary to obtain their medications. In economic terms, this means that demand for some prescription drugs is highly inelastic: the quantity demanded does not drop significantly even if prices rise. Drug manufacturers, therefore, spend enormous sums to develop and market new drugs, recognizing that they likely will be able to charge prices that will ultimately generate substantial profits for their investors. Of course, if the profit incentive was completely removed from drug manufacturers, much of the research and

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[1] As used herein, Patients refers to two groups of persons as follows: (1) Persons who were prescribed drugs manufactured by any Defendants which were subject to Defendants' Average Wholesale Price scheme as alleged herein and who paid for such drugs out of pocket, and (2) Persons who were prescribed such drugs and incurred an obligation for co-payment (or actually made co-payments) under either a government or private insurance program where the amount of co-payment was based on the total reimbursement by the government or private insurer.

development that now takes place would vanish. Thus, the optimal market would both reward innovative drug manufacturers and keep prices as affordable as possible. Balancing these worthwhile goals can be difficult and, unfortunately, abuses take place that have unfairly gouged consumers and injured the State and its Medicaid program as described below. The Attorney General seeks to enjoin and remedy these abuses.

A. The Defendants' Unlawful Scheme

4. The standard practice in the pharmaceutical industry is that the federal Medicare Program, state Medicaid agencies, and certain patients reimburse physicians and pharmacies for hundreds of prescription drugs based upon the Average Wholesale Price ("AWP"), as published and reported by third-party publications such as First Data Bank, Red Book, Blue Book, or Medispan.

5. Physicians and pharmacies purchase the prescription drugs for which they are reimbursed directly from the pharmaceutical manufacturer or indirectly through wholesalers.

6. The AWP is generally not independently determined by the First Data Bank or other third-party reporting agencies. Rather, as part of the AWP Scheme described in this Complaint, pharmaceutical companies purportedly "self-police" and "self-report" the AWP to third-party publications (such as First Data Bank), which then publish the purported AWP, as provided to them by the pharmaceutical manufacturers.

7. Pursuant to federal regulation and industry and State practice, reimbursement for prescription drugs is based primarily upon the reported AWP, and this is true for both Medicare and Medicaid reimbursement.

8. In fact, as an extensive and ongoing Congressional investigation has recently revealed, numerous pharmaceutical manufacturers (including each of the Defendants named herein as well as others not yet named herein) have engaged in a scheme involving the fraudulent reporting of fictitious AWP for certain prescription pharmaceuticals including but not limited to prescription pharmaceuticals covered by Medicare and Medicaid.

9. Specifically, Defendants' AWP Scheme involves the reporting by each Defendant of inflated Average Wholesale Prices. The fraudulent reporting of Average Wholesale Prices has the effect of materially misrepresenting the actual prices paid to Defendants by physicians and pharmacies for prescription drugs.

10. Plaintiff alleges upon information and belief that, in many instances, the purported AWP reported by the Defendant pharmaceutical manufacturers bears little or no relationship to the prices actually paid by physicians or pharmacies.

11. In addition, while federal Medicaid law requires the Defendants to provide quarterly rebates to the State of Montana if they charge the State more than the lowest or "best price" offered to any commercial customer, the Defendants routinely failed to do so as a direct result of the AWP Scheme.

12. As a result of the fraudulent and illegal manipulation of AWP for certain drugs by the Defendant pharmaceutical manufacturers, they and the other manufacturers have reaped tens of millions of dollars in illegal profits at the expense of American governmental payors and consumers, including the State of Montana, and Patients who are residents of the State of Montana. In particular, the elderly who are on Medicare bear the burden of this scheme as they make payments or co-payments based on the fictitious AWP charges.

B. The Damages Caused By Defendants' Illegal Conduct

13. The intended and foreseeable consequences of the Defendants' scheme are several and far reaching, including but not limited to increased drug costs to the State of Montana and its agencies, and increased drug costs to Patients who are Montana residents.

1. Damages to the State of Montana

14. One of the foreseeable and intended consequences of Defendants' conduct has been to unjustly enrich the Defendants at the expense of Montana's health care system, the state health care authority, and ultimately, all Montana residents and taxpayers.

15. In particular, the AWP Scheme has cost the State of Montana millions of dollars in excess Medicaid payments made for medications as a direct result of the illegal AWP Scheme.

16. In addition, the AWP Scheme has cost the State of Montana millions of dollars in excess drug costs for the public employees for whom it provides health care.

17. Finally, numerous state agencies purchase medications at illegally inflated prices based on the AWP Scheme.

18. The State seeks to recover these costs as actual damages and/or restitution in this case.

2. Damages to Patients

19. As further intended and foreseeable effects of the Defendants' AWP Scheme, many private persons residing in Montana also suffered losses.

20. The general public, who must make co-payments for drugs based upon these inflated AWP prices, suffered immense damages. A major group of consumers adversely impacted by this practice are the elderly, who make co-payments as part of Medicare.

21. Through its *parens patriae* and statutory powers, the State of Montana also seeks restitution of these losses in this case.

C. The Objectives Of This Action

22. In this action, the Attorney General seeks to secure for the people of the State of Montana a fair and open market, free from unfair or deceptive acts or practices, and to enable Patients in this State to better shoulder the financial burden of necessary medications.

23. In addition, the Attorney General brings this action to return to the State and its resident Patients the increased medication costs caused by Defendants' wrongful conduct and to disgorge Defendants' excessive profits from the artificially inflated AWP Scheme accomplished through violations of state law.

II. PARTIES

PLAINTIFF

24. This action is brought for and on behalf of the State of Montana and damaged persons and entities within the State of Montana, by Mike McGrath, Attorney General of the State of Montana, pursuant to, *inter alia*, the provisions of the Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. § 30-14-101 et seq., Montana's Medicaid Fraud Statute, Mont. Code Ann. § 53-6-101, et seq., Montana's False Claims statute, Mont. Code Ann. § 17-8-231, and the common law and statutory authority of the Attorney General to represent the State of Montana and its residents.

25. The Montana Medicaid Program offers health care to the Medicaid categorically needy, who are eligible to receive cash assistance under Title XIX. Included in this category are aged, blind and disabled clients, pregnant women to 133 percent of the federal poverty level ("FPL") and children to 100 percent of the FPL. Roughly 45 percent of Montana's Medicaid expenditures are for this category.

26. The Medicaid Montana Program also offers benefits to a category of clients called "Medicaid Medically Needy." This group has some additional income and their need for assistance usually arises from critical medical needs and/or high medical bills.

27. Many low income pregnant women are eligible for Medicaid, and the program is the largest provider of health care in the State of Montana.

28. Montana Medicaid is required by federal law to provide certain basic services. Montana has elected to provide additional coverage, including outpatient drugs and durable medical equipment ("DME"). Drug reimbursements are typically in excess of 10 percent of Montana Medicaid's Annual expenditures, and in 2001 pharmacy costs exceeded $51 million and were the largest single cost item.

DEFENDANTS

29. Defendant Abbott Laboratories, Inc. ("Abbott") is a highly diversified health care company whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Abbott conducts extensive business in the State of Montana, including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein, including such medications as Calcijex® (treatment for kidney failure) and Methapred® (a corticosteroid) that are distributed by Medicaid providers.

30. Defendant American Home Products Corporation ("AHP") is the parent company of Wyeth Worldwide. It is organized and exists under the laws of the state of New Jersey. American Home Products is one of the largest pharmaceutical and health care product companies in the world. Its annual sales in 2000 exceeded $13.3 billion. Through its subsidiaries, AHP manufactures and distributes prescription drugs, including Ativan® (convulsive disorder medication), for clinical distribution by Medicare providers nationwide, and sells Premarin® in the state.

31. Defendant Amgen, Inc. is a corporation organized and existing under the laws of the state of California. Amgen is in the business of manufacturing and distributing prescription pharmaceuticals, including Epogen/Procrit® (for treatment of anemia) and Neupogen® (bone marrow transplant infection prevention), and Aransep (anemia in kidney patients) for clinical distribution by Medicare providers nationwide. In 2000, Amgen's revenues exceeded $3.6 billion.

32. Defendant AstraZeneca US is a corporation organized and existing under the laws of the state of Delaware. AstraZeneca is in the business of manufacturing and distributing prescription pharmaceuticals, including Zoladex® and Casdex (for prostate cancer), for clinical distribution by Medicare providers nationwide.

33. Defendant Aventis Pharma ("Aventis") is a corporation organized and existing under the laws of the state of New Jersey and operating in more than 120 countries in the world. Aventis is in the business of manufacturing and distributing prescription pharmaceuticals,

including Pentacarinat® (pneumonia treatment), for clinical distribution by Medicare providers nationwide. In 1999, Aventis's *pro forma* sales for its pharmaceuticals were $3.3 billion.

34. Defendant Chiron is a corporation organized and existing under the laws of the state of California. Chiron is in the business of manufacturing pharmaceuticals, including Depocyt® (anticancer drug), among other prescription drugs, to Medicare clinical outsourcers. Revenues for 2000 were $972 million.

35. Defendant Baxter Pharmaceutical Products, Inc. ("Baxter Pharmaceutical") is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products and services, including pharmaceuticals such as Gammagard® which are distributed to Medicaid providers.

36. Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is a corporation organized in Delaware with a principal place of business located at 345 Park Avenue, New York, New York. Bristol-Myers manufactures and distributes prescription drugs, including Blenoxane® and Taxol® and other injectible cancer treatment drugs, that are clinically distributed by Medicare providers nationwide. Bristol-Myers' sales for the year 2000 were more than $21 billion worldwide.

37. Defendant Dey, Inc. ("Dey") is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products and services, including pharmaceuticals. Dey manufactures and distributes, among other drugs, Albuterol® solution, used and distributed by Medicare providers.

38. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline Corporation ("GSK") is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products and services, including pharmaceuticals. GSK conducts extensive business in the state of Montana, including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein. This Court has personal jurisdiction over GSK and venue is properly laid in this County. GSK includes that corporation that did business as Glaxo Wellcome, Inc. ("Glaxo"), which was a highly diversified

health care company whose principal business was the development, manufacture and sale of health care products and services, including pharmaceuticals. Glaxo, at time relevant to this complaint, conducted extensive business in the state of Montana, including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein. This Court would have personal jurisdiction over Glaxo to the extent GSK is not responsible as the surviving entity and venue is properly laid in this County. GSK manufactures prescription drugs, including Zovirax®, Alkeran®, Hycamtis® and other cancer and HIV drugs, clinically distributed by Medicare providers nationwide. GSK's annual pharmaceutical sales for the year 2000 were more than $23.5 billion. Every second, more than 30 doses of vaccines are distributed by GSK.

39. Defendant Pharmacia Corporation ("Pharmacia") is a corporation and existing under the laws of the state of New Jersey. Pharmacia's corporate headquarters are located at 100 Route 206 North, Peapack, New Jersey. Pharmacia manufactures prescription drugs, including HIV and cancer treatment drugs (Amikin®, Neosar®, Toposar®, and Andrucil®), for clinical distribution by Medicare and Medicaid providers nationwide. Sales for the colorectal treatment drug, Camptosar®, and the breast cancer treatment drug, Ellence®, were $441 million for the year 2000.

40. Defendant Hoechst Marion Roussel, Inc. ("HMR") is a wholly-owned subsidiary of Aventis S.A. (former Hoechst AG). HMR is a corporation organized and existing under the laws of the state of Delaware, and has its headquarters located at 10236 Marion Park Drive, Kansas City, Missouri. HMR develops and manufactures prescription drugs including Lasix® (high blood pressure treatment) for clinical distribution by Medicare providers nationwide.

41. Defendant Immunex Corporation is a corporation organized and existing under the laws of the state of Washington. Its principal place of business is located at 51 University Street, Seattle, Washington. Immunex manufactures immune system disorder and cancer treatment prescription drugs, including Novantrone® for clinical distribution by Medicare providers nationwide. Immunex's total revenues for 1999 were $542 million.

42. Defendant Eli Lilly and Company ("Lilly") is a corporation organized and existing under the laws of the state of Indiana. Lilly is in the business of manufacturing prescription drugs, such as Nebcin® (for bacterial eye infection treatment), Vancocin® (bacterial infection treatment), and Oncovin® (for the treatment of some cancerous conditions) for clinical distribution by Medicare providers nationwide.

43. Defendant Schering-Plough Corp. is a corporation organized and existing under the laws of the state of New Jersey. Its headquarters are located at 2000 Galloping Hill Rd., Kenilworth, New Jersey. Schering-Plough manufactures prescription drugs, including Garamycin® (eye infection treatment), IntronA® (cancer) and Temodar® (cancer) for distribution by Medicare providers nationwide.

44. Defendant Pharmacia & Upjohn Company ("Pharmacia Upjohn") is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products and services, including pharmaceuticals.

45. SmithKline Beecham Corporation ("SmithKline") was a highly diversified health care company whose principal business was the development, manufacture and sale of health care products and services, including pharmaceuticals. It is now part of GSK. SmithKline conducted extensive business in the State of Montana, including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein. This Court has personal jurisdiction over SmithKline and venue is properly laid in this county, to the extent GSK is not responsible for the wrongful acts of SmithKline.

46. Defendant Warrick Pharmaceuticals Corporation ("Warrick") is a corporation organized under the laws of Delaware with its principal place of business in Reno, Nevada. Defendant Warrick manufactures and distributes Albuterol® solution used by Medicare providers.

CO-CONSPIRATORS AND DOE DEFENDANTS

47. Various other individuals, partnerships, sole proprietors, business entities, companies, and corporations, presently unknown to the State and not named as defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities acted as co-conspirators and aided, abetted, or participated with Defendants in the commission of the wrongful acts alleged herein or otherwise caused the damages suffered by the State and its residents.

48. DOES 1-100 are corporations, companies, partnerships, or other business entities that participated in the illegal course of conduct that is the subject of this action as alleged herein.

49. DOES 101-125 are residents of the state of Montana and are officers, employees, or agents of the Defendants and/or entities owned or controlled by the Defendants. DOES 101-125 participated in the illegal course of conduct that is the subject of this action as alleged herein.

50. DOES 126-150 are residents of states other than the state of Montana and are officers, employees, or agents of the Defendants and/or entities owned or controlled by the Defendants. DOES 126-150 participated in the illegal course of conduct that is the subject of this action as alleged herein.

51. DOES 151-200 are residents of countries other than the United States and are officers, employees, or agents of the Defendants and/or entities owned or controlled by the Defendants. DOES 151-200 participated in the illegal course of conduct that is the subject of this action as alleged herein.

52. Except as described herein, Plaintiffs are, as yet, ignorant of the true names, capacities, nature and extent of the participation in the course of conduct alleged herein of the persons sued as DOES 1-200 inclusive and, therefore, sues these Defendants by such fictitious names. The State will amend this Complaint to allege the true names and capacities of the Doe Defendants when ascertained.

53. In addition, Defendants unknown at this time may include independent physicians and other medical providers who prescribed Covered Drugs and engaged in fraudulent billing practices, as well as various other persons, partnerships, sole proprietors, firms, corporations and individuals that may have participated as co-conspirators with Defendants in the offenses alleged in this Complaint and may have performed acts and made statements in furtherance of the alleged illegal conduct.

54. Each of the Defendants designated herein as a Doe Defendant is legally responsible in some manner for the unlawful acts referred to herein. Plaintiff will seek leave of Court to amend this Complaint to reflect the true names and capacities of the Defendants designated herein as Does when such identities become known. Collectively, these companies are referred to as the "Pharmaceutical Defendants" or Defendants.

55. Each of the Defendants named above participated in the Medicaid Rebate Program.

56. At all times relevant hereto, each of the Defendants transacted business in the state of Montana, including but not limited to, selling and distributing products in the State.

III. THE MEDICARE INSURANCE PROGRAM

57. America's prescription drug prices, already the highest in the world, have risen nearly three times faster than inflation in the last ten years. This rapid increase has forced some people to make difficult choices between drugs that keep them healthy or other life necessities like food and rent. Although a variety of factors have contributed to the price increases, in some instances the competitive market for prescription drugs has been abused.

58. Many state Medicaid administrators have been placed in the unenviable position of having to ration needed health care services to the poor due to a lack of funds. For example, major newspapers such as the Washington Post reported that the Clinton Administration abandoned its effort to extend Medicaid coverage for AIDS therapies due to the high cost of drugs needed to treat HIV patients (December 5, 1997).

59. While this case is not solely about Medicare, the Medicare program and its method of using AWP as a basis for reimbursement is an important factual predicate to the scheme alleged herein.

60. In 1965, Congress enacted Title XVIII of the Social Security Act (known as "Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

61. The Department of Health and Human Services ("HHS") is an agency of the United States Government that is responsible for the funding, administration and supervision of the Medicare Program. At all relevant times, the Health Care Financing Administration ("HCFA") was a division of HHS, now known as the Center for Medicare and Medicaid Services ("CMS"), and was directly responsible for the administration of the Medicare Program.

62. As a general matter, the Medicare Program does not cover the cost of prescription pharmaceuticals that a Medicare beneficiary obtains pursuant to a prescription and thereafter self-administers (e.g., by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, namely, those that cannot be self-administered and are furnished incident to a physician's services, including injectables that are administered by a medical provider.

63. Medicare calculates the "allowable amount" (i.e., the amount that Medicare will pay) based upon the payment methodology set forth in 42 C.F.R. § 405.517, which regulation was published in the Federal Register on November 25, 1991, and became effective on or about January 1, 1992. Section 405.517 provides:

> Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.
>
> (a) Applicability. Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician's service, a drug or biological furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.
>
> (b) Methodology. Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual

> charge on the Medicare benefits or ***95 percent of the national average wholesale price of the drug or biological***.
>
> (c) Multiple-source drugs. For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. (Emphasis added.)

64. Medicare and many Medicaid programs and other Third-Party Payors base reimbursement to physicians and other providers of drugs on AWP. AWPs are published for each drug identified by a National Drug Code ("NDC").[2] Manufacturers periodically report AWPs for NDCs to publishers of drug pricing data, such as Medical Economics Company, Inc., which publishes the Red Book, or First Data Bank, which compiles the National Drug Data File. Publishers of AWPs and other drug prices state that they list the prices reported to them by the manufacturers. There is no required frequency for manufacturers to report AWPs, but publishers claim that they attempt to update AWPs at least annually. Medicare carriers, the contractors responsible for paying Part B claims, use published AWPs to determine the Medicare-allowed amount, or payment level, which is 95 percent of AWP for each HCPCS-coded drug.[3]

65. Physicians are able to obtain drugs at prices significantly below current Medicare reimbursements. The widely available prices that are available from wholesalers and group purchasing organizations ("GPOs") for physician-administered drugs are considerably less than AWPs used to establish the Medicare payment. For most of the high-expenditure or high-volume physician-administered drugs, widely available discounts from AWP ranged from 13 percent to 34 percent. Physicians who have been identified as low-volume billers for oncology drugs can also purchase drugs for considerably less than Medicare's payment. In addition to

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[2] NDCs are the universal product identifiers for drugs for human use; the Food and Drug Administration assigns the first part of the NDC, which identifies the firm that manufactures, repackages, or distributes a drug. Each NDC is specific to a chemical entity, dosage form, manufacturer, strength, and packages size. For example, a drug made by one manufacturer, in one form and strength, but in three package sizes would have three NDCs.

[3] HDPCS is the Health Care Financing Administration Common Procedure Coding System, as maintained and distributed by the Department of Health and Human Services.

receiving reimbursement for drugs, physicians are paid separately for services associated with drug administration under the Medicare physician fee schedule.

66. Prior to January 1, 1998, the Medicare Part B "allowed amount" was interpreted as being the lower of the "estimated acquisition cost" ***or*** 95% of the "national average wholesale price," i.e., the AWP for the drug. The estimated acquisition cost for a drug could be determined by the Medicare Program "based on surveys of the actual invoice prices paid for the drug," taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically the AWP published in the First Data Bank and similar publications has been used to determine Medicare reimbursement.

67. In determining the AWP, HCFA uses the AWP published in industry publications such as First Data Bank, Blue Book, or Medispan as the basis for reimbursement. Specifically, in PM AB-99-63 (as of January 1, 1998), HCFA stated that it will pay drug and biologicals based on the lower of the actual billed charge or 95 percent of the AWP reflected in pharmaceutical industry publication sources such as Red Book, Blue Book, or Medispan.

68. In fact, and by common understanding, usage and practice in the industry, Medicare, Medicaid and other providers have continued to determine the allowable payment for a prescription drug based upon the AWP reported by the applicable pharmaceutical manufacturer. This is due, in large measure, to practical problems with ascertaining "actual" or "estimated acquisition cost" charges, given necessary adjustments for the enumerated factors such as spoilage, waste, and inventory.

69. Medicare Part B reimburses medical providers for 80 percent of the allowable amount. The remaining 20 percent is paid by the Medicare beneficiary and is called the "co-payment" amount. In addition, beneficiaries under Medicare Part B are required to pay an annual deductible amount before Part B benefits are payable.

70. Throughout the 1990s, the Red Book and other publications such as Blue Book and Medispan published AWPs for pharmaceuticals. The Red Book and other publications simply publish the prices that are supplied to them by the pharmaceutical manufacturers,

including Defendants, generally without independent verification. Defendants knew that they could directly control and fraudulently inflate the AWP for pharmaceuticals at any time by simply forwarding a higher, fictitious AWP to the Red Book or other publication.

71. The actual price that providers pay for Medicare Part B drugs is not disclosed to the State and certainly not to patients. Physicians and suppliers may belong to "GPOs" that pool the purchase of multiple entities to negotiate prices with wholesalers or manufacturers. GPOs may negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals. In addition, providers can purchase Part B-covered drugs from general or specialty pharmaceutical wholesalers or they can have direct purchase agreements with manufacturers.

72. Certain practices involving these various entities has resulted in prices paid at the time of sale that do not reflect the final net cost to the purchaser. Manufacturers or wholesalers offer purchasers rebates based on the volume of products purchased not in a single sale but over a period of time. Manufacturers also establish "chargeback" arrangements for end purchasers, which result in the AWP overstating what those purchasers pay. Under these arrangements, the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler provides the product to the purchaser for the lower negotiated price, and the manufacturer then pays the wholesaler the difference between the wholesale price and the negotiated price.

73. Most manufacturers sell drug products to physicians at a discount from AWP. Sometimes these discounts are substantial. As noted herein, under Medicare rules physicians are permitted to bill for such drugs at 95 percent of AWP, regardless of the drug's cost to the physician. This practice of taking advantage of the difference between the physician's purchase price and the amount that a physician is permitted to bill Medicare is referred to internally by Defendants as "marketing the spread."

74. There is a wide disparity between a drug's estimated acquisition cost and Medicare's payment for that drug. Physician-billed drugs account for the bulk of Medicare

spending on Part B drugs. Of those billed by physicians, drugs used to treat cancer accounted for most of Medicare's expenditures.

75. In a September 21, 2000, report, the United States Government Accounting Office ("GAO") found that:

> Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.
>
> For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger – 65 percent and 86 percent less than AWP.

76. Two drugs, albuterol and ipratropium bromide for respiratory conditions, account for most of the pharmacy-supplied drugs paid for by Medicare. In 2001, they were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP.

77. Two of the four high-volume oral immunosuppressives were available from wholesalers with average discounts of 14 percent and 77 percent. Wholesale price information on the other two was not available, but retail prices from online pharmacies were as much as 13 percent and 8 percent below AWP.

78. According to the GAO report, the discounts on physician-billed drugs, based on wholesaler and the GPOs' catalogue prices, are notably lower than Medicare's payment, which reflects a discount of five (5) percent below AWP. The discounts indicate that, on a national level, Medicare's payments for these drugs were ***at least $532 million higher*** than providers' acquisition costs in just the year 2000. Further, the discounts reported may only be the starting point for additional discounts provided to certain purchasers, as chargebacks, rebates, and other discounts may drive down the final sale price.

79. The following table illustrates some of the discounts provided to physicians[4]:

Table 1: Widely Available Discounts From AWP for Medicare-Covered Drugs Billed Primarily by Physicians, 2001

Drug name	Specialty most frequently billed for drug	Average AWP[a]	Average widely available discount from AWP (percentage)[b]
Leuprolide acetate (for depot suspension)	urology	$618.93	17.6
Rituximab	oncology[c]	$478.47	19.2
Goserelin acetate implant	urology	$469.99	21.9
Docetaxel	oncology	$313.51	22.0
Filgrastim (G-CSF) 480 mcg	oncology	$300.40	18.0[d]
Pamidronate disodium	oncology	$279.86	16.8
Hylan G-F 20	orthopedic surgery	$225.13	17.7[d]
Filgrastim (G-CSF) 300 mcg	oncology	$193.62	18.4[d]
Paclitaxel	oncology	$180.57	19.0
Irinotecan	oncology	$141.32	22.9
Carboplatin	oncology	$120.48	20.3
Gemcitabine HCI	oncology	$112.34	21.3
Dolasetron mesylate, injection	oncology	$45.02	65.0[d]
Granisetron HCI, injection	oncology	$19.52	29.3
Leucovorin calcium	oncology	$18.44	85.6
Epoetin alpha for non-ESRD use	oncology	$12.91	15.2
Ondansetron HCI, injection	oncology	$6.41	12.8
Botulinum toxin type A	neurology	$4.86	N/a[e]
Imiglucerase	oncology	$3.95	N/a[e]
Dexamethasone sodium phosphate	oncology	$1.44	14.2
Heparin sodium	oncology	$0.43	34.4

[a]"Average AWP" is the average of AWP of each NDC for that product adjusted to the HCPCS-defined dosage.

[b]"Average widely available discount from AWP" for each drug was calculated by (1) determining the average widely available price(s) for each NDC for that drug, (2) determining the percentage difference between the average widely available price(s) and the AWP for each NDC for the drug, and (3) averaging the percentage differences for all NDCs for that drug.

[c]"Oncology" specialty includes hematology/oncology and medical oncology.

[4] Source: September 2001 GAO Report 01-1118.

80. The "spread" is so significant that in some instances a patient's 20 percent co-payment is more than the cost of the drug to the doctor or provider, as evidenced in the table below[5]:

Drug	HCPCS Code	1999 Florida Medicare Allowable	20% Co-Payment	1999 Wholesale Cost
Leucovorin 50mg	J0640	$19.50	$3.90	$1.48
Gentamycin 80mg	J1580	$4.74	$0.95	$0.56
Sodidum Chloride 0.9% 500ml	J7040	$10.30	$2.06	$1.46
5% Dextrose/Sodium Chloride 0.9% 500ml	J7042	$10.75	$2.15	$2.00
Sodium Chloride 0.9% 250ml	J7050	$10.90	$2.18	$1.33
5% Dextrose in Water 500ml	J7060	$9.73	$1.95	$1.50
Lacted Ringers 1000ml	J7120	$12.67	$2.53	$2.25
Doxorubicin 10mg	J9000	$46.42	$9.28	$6.10
Cyclophosphamide Lyophillzed	j9096	$48.85	$9.77	$9.95
Etoposide 10mg	J9181	$12.93	$2.59	$0.75
Etoposide 100mg	J9182	$129.34	$25.87	$7.50
Vincristine 1mg	J9370	$30.16	$6.03	$3.50
Vincristine 2mg	J9375	$33.33	$6.67	$5.95

[5] Source: Stark Investigative Materials

81. Examples of the manipulation of AWP are contained in the investigative materials compiled by Congressman Pete Stark (D-Calif.):

(a) In the 2000 edition of the Red Book, Defendant Bristol reported an AWP of $1,296.64 for one 20mg/ml, 50ml vial of Vepesid (Etoposide) for injection, while selling the exact same drug in the same quantity to a GPO for $70. This represents a spread between Bristol's falsely inflated AWP and the real price of $1,226.64.

(b) As the following excerpts from Bristol's own documents reveal, Bristol's earlier participation in the false price manipulation scheme with respect to Etoposide (Vepesid) interfered with physicians' medical decisions to use Etopophos: "The Etopophos product profile is significantly superior to that of etoposide injection. . . . Currently, physician practice can take advantage of the growing disparity between VePesid's [name brand for Etoposide] list price (and, subsequently, the Average Wholesale Price [AWP] and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished."

(c) Thus, Defendant Bristol acknowledges that financial inducements influence the professional judgment of physicians and other healthcare providers. Bristol's strategy of increasing the sales of its drugs by enriching, with taxpayer dollars, the physicians and others who administer drugs is reprehensible and a blatant abuse of the privileges that Bristol enjoys as a major pharmaceutical manufacturer in the United States.

(d) Bristol employed a number of other financial inducements to stimulate the sales of its drugs at the expense of the Medicare and Medicaid Programs that were concealed from the U.S. Government and the State of Montana. Such inducements included volume discounts, rebates, off-invoice pricing and free goods designed to lower the net cost to the purchaser while concealing the actual cost of the drug from reimbursement officials. For example, Bristol provided free Etopophos to Drs. Lessner and Troner in exchange for these Miami, Florida, oncologists' agreement to purchase other Bristol cancer drugs. This arrangement had the effect of lowering the net cost of the cancer drugs to the oncologists and

creating an even greater spread than would already result from the invoiced prices. The value of the free goods is often significant. Similarly, other documents show that Bristol provided free Cytogards in order to create a lower than invoice cost to physicians that purchased other cancer drugs through the Oncology Therapeutic Network.

(e) The above-referenced free goods examples created financial incentives to the physicians that were over and above the spread created by the difference between Bristol's reported prices and regular prices provided to the market.

(f) Bristol's price manipulation scheme was directed at both the Medicare and Medicaid Programs. Bristol commonly reported prices directly to Medicare carriers as well as state Medicaid Programs.

(g) Defendant Glaxo was no different, as evidenced in a letter from SmithKline. In an apparent effort to increase reimbursement to physicians and clinics, effective January 10, 1995, Defendant Glaxo increased the AWP for Zofran by 8.5 percent while simultaneously fully discounting this increase to physicians. The net effect of these adjustments was to increase the amount of reimbursements available to physicians from Medicare and other Third-Party Payors whose reimbursement is based on the AWP. Because the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in the AWP was designed to increase revenue per unit to Glaxo. Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other Third-Party Payors.

(h) Defendant Pharmacia also engaged in use of inflated AWP; for example, it wrote to an oncology clinic boasting of the savings offered off AWP:

> Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers [the clinic] a reimbursement of over $8,000,000 profit when reimbursed at AWP.

(i) Defendant Bayer acknowledged the AWP Scheme in an internal e-mail message, stating that "many" health care providers are "paid on a discount from AW[P]."

(j) In a document entitled "Confidential Baxter Internal Use Only," Defendant Baxter admitted to the impact of the AWP Scheme:

> Increasing AWP's was a large part of our negotiations with the large homecare companies.
>
> Homecare companies that reimburse based on AWP make a significantly larger margin . . . .

(k) TAP offered free samples to doctors to effectuate the AWP Scheme. According to an indictment issued by the U.S. Attorney in Boston, Dr. SF was a urologist with a principal place of business in the San Francisco area in California. Dr. SF from time to time in the 1990s diagnosed and treated patients suffering from prostate cancer, many of whom were insured by the Medicare Program. As a part of the treatment of some of those patients, and beginning as early as 1993, Dr. SF prescribed Lupron. Dr. SF informed the sales representatives calling upon Dr. SF, who so informed TAP employees, that he would switch his business and prescribe Zoladex to his patients suffering from prostate cancer if TAP and its employees did not provide him financial incentives that were being provided to him by another company. In order to prevent Dr. SF from switching his patients to Zoladex, and as an inducement to him to continue to purchase Lupron and to prescribe that drug to his patients, many of whom were insured by the Medicare Program, TAP authorized its sales representatives calling upon Dr. SF to give to him free samples of Lupron. At times, TAP approved giving Dr. SF ten free samples in exchange for each order by him of more than 100 one-month injections of Lupron, and at times, TAP's corporate headquarters authorized those free samples for Dr. SF. Beginning in or about July 1994 and continuing through in or about December 1997, TAP sales representatives gave to Dr. SF more than 85 one-month doses of Lupron for free, on or about the dates indicated in the following chart:

Date	Quantity
7/1/94	10
1/27/95	10
7/22/95	10
11/20/95	10
8/9/96	10
4/16/97	15
12/11/97	20

These 85 samples, more or less, were given by sales representatives as an inducement to get and keep his business. That doctor thereafter prescribed and administered these free dosages to patients insured by the Medicare Program and other insurance companies and submitted claims to those insurers and the patients for the prescription of these free dosages to turn those samples into a cash kickback and rebate. These free samples were not used by TAP in calculating AWP.

(l) Other examples include the following:

Adriamycin, an antibiotic used in cancer treatment and manufactured by Pharmacia, had an AWP of $241.36 as of April 2000. The real wholesale price was $33.43. In 1997, when the reported AWP for this drug was $946.94, it was being offered to physicians for as low as $152.00.

Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of $54.56. The actual best price was $6.75.

Toposar, also manufactured by Pharmacia, is used to treat testicular and lung cancer. Its AWP as of April 2000 was $28.38; DOJ found that retailers were buying it for $1.70.

Vancomycin, an antibiotic used to treat intestinal infections and manufactured by Abbott, had an AWP of $68.77 as of April 2000. DOJ adjusted it to $8.14.

82. Upon information and belief, each of the Defendant pharmaceutical companies has also utilized a large array of other inducements to stimulate sales of their drugs. These inducements, including "educational grants," volume discounts, and rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at $100 for ten units of a drug item might really only cost the purchaser one-half that amount. If we assume a subsequent shipment of an additional ten units at no charge, or a "grant," "rebate" or "credit memo" in the amount of $50, the transaction would truly cost just $5 per unit net. Through all these "off-invoice" means, drug purchasers were provided the substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price--the price that corresponded to reported AWPs and inflated reimbursement from Medicaid and Medicare. Some examples of this are set forth below:

> BAYER: "I have been told that our present Kogennate price, $.66, is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of $.60 to $.62 to secure this volume. From Quantum's stand point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."
>
> BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the 4.81 price. They have requested that we send them free product every quarter calculated by looking at the number of

> units purchased in that quarter and the $.13 reduction in price . . . . free product given to achieve overall price reduction."[6]

83. In 2000, state and federal investigators challenged the reported AWP of various drugs. Thereafter Abbott lowered its reported AWP on various drugs, thereby admitting that prior reported AWPs were artificially inflated.

84. Among those directly harmed by the Defendants' manipulation of the AWP in the Medicare context are Montana residents who, as Patients, have been compelled to pay excessive co-payments for medications based upon the falsely inflated AWPs.

IV. THE AWP SCHEME ALSO INFLICTS DAMAGES ON THE STATE OF MONTANA

85. The damages inflicted by the AWP Scheme are not confined to Medicare payors.

86. In addition, numerous State agencies have overpaid for medications based upon the fraudulently reported AWPs.

87. Likewise, most Medicaid payors including the State of Montana historically have also typically based reimbursement on the AWP.

88. On August 10, 2001, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG"), reported the results of a survey of 216 pharmacies in eight states and obtained 16,024 invoices for brand name drug products. The OIG report concluded that nationally, pharmacy cost was 21.84 percent below AWP, a 19.3 percent increase from 1994. This report further concluded that although many states paid a discount of 10 percent off AWP, this was not sufficient to "ensure that a reasonable price is paid for drugs."

89. Recently, Defendant Bayer agreed to settle claims asserted by the U.S. Government arising from this practice. According to the Department of Justice's litigation release:

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[6] Source: Attachments to U.S. House committee on Ways and Means correspondence dated September 28, 2000.

> The government's investigation of the allegations revealed that Bayer beginning in the early 1990s falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state and federal governments to set reimbursement rates for the federally and state funded Medicaid Program. By setting an extremely high AWP and, subsequently, selling the product to doctors at a dramatic discount, Bayer enabled physicians to receive excess reimbursement from private and government insurers. The Bayer AWPs, at issue in the investigation, involved several of Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases.
>
> The investigation further revealed that Bayer was engaging in a practice referred to as "marketing the spread" that also has the effect of discouraging market competition from companies that do not inflate AWPs as a way of attracting doctors to their products. The department's probe also showed that some physicians and home health companies ignore the products of companies that refuse to create these profit windfalls for customers.
>
> The parties also are settling allegations that Bayer knowingly underpaid the Medicaid Program for rebates owed by it to the states. The Medicaid Rebate program was initiated in 1991 to require drug companies to pay quarterly rebates to states in a way that accounts for discounts that drug companies give to customers. Under the program, Bayer was required to report the best price offered to any commercial, for-profit customer to the government and calculate a quarterly rebate based, in part, upon the best price. The investigation revealed that certain of Bayer's customers received discounts unaccounted for by the multi-national pharmaceutical company in its quarterly best price calculations thereby allowing Bayer to underpay the rebates it owed.

90. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products compensated under a state's Medicaid Program, the manufacturer had to enter into a rebate agreement with the Secretary of Health and Human Services. Pursuant to the rebate agreement, the manufacturer promised to report to the Medicaid Program its best price. The statute defines the best price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity." The section also provides that "best price" includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates" and does not include "prices that are merely nominal in amount."

91. Each Defendant entered into a Rebate Agreement with the U.S. Secretary of Health and Human Services. In that agreement, each agreed to comply with Section 1396r-8, and hence:

(a) Agreed to report its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates where necessary;

(b) Agreed that it would determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid"; and

(c) Agreed that the best price would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

92. After execution of this agreement, each Defendant reported its average manufacturer's price in each quarter to the Medicaid Program.

93. In keeping with their artificial inflation of the AWPs, each Defendant did not report the actual "best price" but, instead, excluded from best price discounts and other inducements offered to physicians to increase use of a drug being reimbursed by governmental entities at AWP.

V. MOTIVATION FOR DEFENDANTS' AWP PRICING SCHEME

94. The purpose and intent of Defendants' fraudulent AWP Scheme is to manipulate and thereby increase the amount of reimbursement received by physicians or other health care providers who prescribe drugs manufactured and sold by Defendants.

95. Specifically, Defendants' AWP Scheme contemplates that (a) Defendants will intentionally report falsely and fraudulently inflated AWP prices for these drugs to industry

publications; and (b) Defendants will actually charge health care providers amounts for these drugs that are substantially less than the AWP that Defendants have fraudulently reported.

96. The health care provider then receives reimbursement from Medicare, Medicaid, or a Third-Party Payor based upon the fraudulently inflated AWP. This circumstance results in a substantial financial incentive to the provider, representing the difference between the inflated AWP-based reimbursement to the provider and the significantly lower direct price charged by Defendants to the health care provider.

97. Defendant pharmaceutical manufacturers refer to the amount received by the health care provider resulting from the difference between the fraudulently inflated AWP reimbursement and the price actually paid by the provider as the "spread."

98. Each of the Defendants has sought to manipulate the market for drugs covered by Part B by inducing health care providers to prescribe these drugs, rather than competing drugs, because of the higher "spread" resulting from the falsely and fraudulently inflated AWP.

99. By participating in the AWP Scheme, Defendants seek to influence doctors to prescribe the drug with the greatest "spread" between the AWP and the actual direct price paid by the provider to the manufacturer. In fact, Defendants have greatly increased their market share and resulting profits by manipulating the AWP to create falsely inflated "spreads" and resulting financial incentives to providers to prescribe specific drugs subject to the AWP Scheme.

100. The manipulation of AWP at the expense of Medicare, Medicaid and their respective patients is further revealed when the Defendants sell drugs that are not reimbursed by Medicare or Medicaid. In these circumstances, the drug companies often report accurate AWPs and actually compete with other drug companies on the basis of having a lower AWP than the other company. The company with the lower AWP will urge physicians to consider the cost to the patient when selecting drugs and promote its lower AWP as a selling tool. Thus, where Medicare and Medicaid are not involved, Defendants often ensure that their AWPs are accurate so as to compete for market share based on price.

101. Defendants were aware that physicians would purchase and utilize products that have the widest spread between the providers' true costs and the reimbursement paid by third parties. All Defendants made representations of their AWP for various drugs, which representations were not accurate. In doing so, Defendants hoped that providers would view the inflated AWP as a reason for selecting their drug. Defendants also knew that this selection would be at the expense of patients who were making a co-payment and at the expense of governmental payors.

102. For example, a GAO report focusing on sales of a drug in Florida found that Medicaid usage of Vancomycin nearly doubled when Abbott raised the AWP. When Bayer retained its spread on Whin Rho while other manufacturers did not, its use "skyrocketed."

103. The AWP Scheme has a profound and dangerous additional effect by influencing some medical practitioners' judgments. This is acknowledged, for example, by Defendant Bristol who developed a second-generation etoposide, namely, Etopophos:

> Bristol: "The Etopohos produce profile is significantly superior to that of etoposide for injection. . . ."
>
> "Currently, physician practices can take advantage of the growing disparity between VePesid's lists price (and, subsequently, the Average Wholesale Price [AWP]) and the actual acquisition cost when obtaining reimbursement for etoposide purchase. If the acquisition price of Etopophos is close to the list price, the physicians' financial incentive for selecting the brand is largely diminished.[7]"

104. This influence is further demonstrated by SmithKline Beecham and TAP:

> SMITHKLINE: "In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP. . . . Therefore, the spread between the AWP and clinic cost represents a profit to the clinic of $50.27 for the medication alone. . . . From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regiments."

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[7] Source: Correspondence from Committee on Ways and Means dated September 28, 2000, to Alan Holmes.

> TAP: "As we have also discussed, Northwest Iowa Urology is very upset about the allowable not going up. I personally met with the doctors to discuss the issue 4/17. The physicians have started using Zoladex but would stop if the allowable issue was taken care of. NWI Urology has 180 patients on Lupron.[8]"

105. Thus, although they are competitors, each of the Defendants agreed to a scheme whereby each would publish in the Red Book, Blue Book and Medispan their artificially inflated "AWP." Each Defendant knew that the AWPs were fictitious, but each one followed course and published their own fictitious AWP pursuant to their express or tacit agreement to do so.

VI. THE CONGRESSIONAL INVESTIGATION

106. The United States Congress has been investigating Defendants' wrongful activities. In a letter sent to each of the Defendants dated October 31, 2000, Congressman Stark stated in pertinent part:

> You should by now be aware of Congressional investigations revealing that Abbott has for many years reported and published inflated and misleading data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing public health . . . . The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price (AWP) and direct price ("DP") which are utilized by the Medicare and Medicaid Programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to in your industry as "the spread." The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims . . . . Based on the evidence collected, Abbott should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly

[8] Source: Id.

> be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their prices, then Congress will be left with no alternative but to take decisive action to protect the public.

107. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the trade organization known as the Pharmaceutical Research and Manufacturers of America, Congressman Stark stated:

> This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit.

108. In his letter, Congressman Stark made the following five "shocking conclusions":

> First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.
>
> Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.
>
> Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
>
> Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.
>
> Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

VII. DIRECT DAMAGE SUSTAINED BY THE STATE OF MONTANA, PATIENTS AND THIRD-PARTY PAYORS

109. Patients are directly damaged by Defendants' AWP Scheme because patients frequently are required to make a co-payment for a pharmaceutical, or because patients occasionally make payment in full. The amount of the co-payment is often a direct function of the overall reimbursement paid on behalf of the patient by Medicare or Third-Party Payors.

110. For example, as alleged herein, Medicare recipients must pay 20 percent of the total amount that is reimbursed by Medicare to the pharmaceutical manufacturer. Thus, if Medicare reimburses $100 for a covered drug based upon the reported AWP, the Medicare beneficiary is responsible for 20 percent (or $20) in this situation.

111. Many Medicare beneficiaries obtain supplemental insurance known as "Medigap" or "Medicare Plus" to cover the costs of pharmaceuticals as well as other costs not paid by Medicare. Such supplemental insurers are also Third-Party Payors who are damaged by the AWP Scheme.

112. The AWP Scheme also affected the State of Montana because, in each instance of a drug payment made under Medicaid, the State paid an inflated amount.

113. Moreover, each of the Defendants has failed to report accurate best price information as required by federal Medicaid law, and thereby deprived the State of its proper rebates. See 42 U.S.C. § 1396r-8.

114. Similarly, numerous State agencies have overpaid for medications based upon the fraudulently reported AWPs.

115. In addition, Third-Party Payors also typically make reimbursement to health care providers for pharmaceuticals based upon the AWP, where Medicare or Medicaid are inapplicable.

116. Although the State knew that, at certain times, the AWP may not have always reflected all of the discounts offered certain providers, the State was not aware of the failure of

Defendants to accurately report "best prices" for rebate purposes and reasonably believed that Defendants were reflecting all discounts in their determination of the "best price."

117. As for patients, they were unaware of the fact of discounts from AWP, the extent of discounts and/or the fact their co-payments or drug payments were based on amounts that did not reflect the true market price.

VIII. CLAIMS FOR RELIEF

COUNT I

UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT

(Violations of § 30-14-101 et seq.)

CLAIM FOR DAMAGES CAUSED TO MONTANA RESIDENTS

118. The State of Montana repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

119. This Claim is brought for restitution of the losses incurred by Montana residents as a result of the AWP Scheme.

120. Defendants' conduct as alleged in this Complaint constitutes deceptive acts or practices in violation of Mont. Code Ann. § 30-14-103 in that:

(a) Defendants have failed to disclose material facts in the conduct of trade or commerce in that they have not disclosed that the AWP does not reflect the true average wholesale price of the drug products they sell, but are instead inflated in order to drive up the prices paid by Patients within the State of Montana;

(b) Defendants have made false or misleading statements of facts concerning the price of goods in that they have lied about the true AWP paid for their medications in order to drive up the prices paid by Patients within the State of Montana;

(c) Defendants have knowingly made false representations in a transaction by representing that the AWP is an accurate reflection of the average wholesale price paid for their drugs; and

(d) Defendants have violated state and federal statutes and regulations relating to the sale or lease of goods including, without limitation, the federal regulations governing the determination of Medicare payments for drugs (42 C.F.R. § 405.517), the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 and 1343, and the Racketeer Influenced and Corrupt Organizations Act (RICO), particularly 18 U.S.C. § 1962(c) and (d).

121. Defendants acted willfully and knowingly in committing the actions set forth above.

122. The wrongful conduct alleged in this Complaint occurs and continues to occur in the ordinary course of Defendants' business or occupation and has caused great harm to the State of Montana and its residents, who were foreseeable and direct victims of Defendants' wrongful conduct.

123. Defendants' violations of the CPA were committed with the intent to mislead and defraud.

124. Defendants' wrongful, deceptive and illegal conduct has resulted in excessive and illegal profits to Defendants and excessive payments made by Patients who are Montana residents.

WHEREFORE, the State of Montana prays as follows:

A. That the Court adjudge and decree that Defendants have engaged in the conduct alleged herein.

B. That the Court adjudge that the conduct is unlawful and in violation of Mont. Code Ann. § 30-14-103.

C. That the Court enjoin and restrain Defendants and their officers, agents, servants, and employees, and those in active concert or participation with them, from continuing to engage in such conduct or other conduct having similar purpose or effect.

D. That the Court enjoin Defendants and order that any and all future disseminations of AWP and "best price" accurately reflect the average wholesale prices paid by physicians and pharmacies.

E. That the Court, pursuant to Mont. Code Ann. § 30-14-131, enter an order restoring to the citizens of this State, all monies acquired by means of Defendants' unlawful practices.

F. That the State of Montana recover from Defendants the costs of this action, including reasonable attorneys' fees.

G. That the Court Order such other and further relief as it may deem just, necessary and appropriate.

COUNT II

DECEPTIVE TRADE PRACTICES

(Violations of § 30-14-101, et seq.)

CLAIM FOR CIVIL PENALTIES, INJUNCTIVE RELIEF, AND RESTITUTION FOR THE STATE OF MONTANA

125. The State of Montana repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

126. This Claim is brought for restitution of the losses suffered by State of Montana as a result of the AWP Scheme and the resulting failure to accurately report the "best price," to recover civil penalties for Defendants' massive violations of Montana law, and to impose injunctive relief ending the unlawful AWP Scheme.

127. Defendants' conduct as alleged in this Complaint constitutes deceptive acts or practices in violation of Mont. Code Ann. § 30-14-103 in that:

(a) Defendants have failed to disclose material facts in the conduct of trade or commerce in that they have not disclosed that the AWP does not reflect the true average wholesale price of the drug products they sell, and that the "best prices" they report are

not the actual "best prices" offered to other commercial entities, but are instead inflated in order to drive up the prices paid for medications by the State of Montana;

(b) Defendants have made false or misleading statements of facts concerning the price of goods in that they have lied about the true AWP and "best prices" paid for their medications in order to drive up the prices paid by the State of Montana;

(c) Defendants have knowingly made false representations in a transaction by representing that the AWP is an accurate reflection of the average wholesale price paid for their drugs, and that their reported "best prices" are in fact the "best prices" offered to a commercial entity for their drugs; and

(d) Defendants have violated state and federal statutes and regulations relating to the sale or lease of goods including, without limitation, the "best price" requirement of the Medicaid statute, the federal regulations governing the determination of Medicare payments for drugs (42 C.F.R. § 405.517), the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 and 1343, and the Racketeer Influenced and Corrupt Organizations Act (RICO), particularly 18 U.S.C. § 1962(c) and (d).

128. Defendants knew or should have known that the actions set forth above violated the CPA.

129. The wrongful conduct alleged in this Complaint occurs and continues to occur in the ordinary course of Defendants' business or occupation and has caused great harm to the State of Montana and its residents.

130. Defendants' violations of the CPA were committed with the intent to mislead and defraud.

131. Defendants' wrongful, deceptive and illegal conduct has resulted in excessive and illegal profits to Defendants and excessive payments by the State of Montana and its residents.

WHEREFORE, the State of Montana prays as follows:

A. That the Court adjudge and decree that Defendants have engaged in the conduct alleged herein.

B. That the Court adjudge that the conduct is unlawful and in violation of Mont. Code Ann. § 30-14-103.

C. That the Court enjoin and restrain Defendants and their officers, agents, servants, and employees, and those in active concert or participation with them, from continuing to engage in such conduct or other conduct having similar purpose or effect.

D. That the Court enjoin Defendants and order that any and all future disseminations of AWP and "best price" accurately reflect the average wholesale prices paid by physicians and pharmacies, and the "best price" offered to any commercial entity, respectively.

E. That, pursuant to Mont. Code Ann. § 30-14-142(2), the Court assess civil penalties of $1,000 from each Defendant for each willful violation of Mont. Code Ann. § 30 14 103 complained of herein.

F. That, pursuant to Mont. Code Ann. § 30-14-103, the Court make such additional orders or judgments as may be necessary to restore to the State all moneys which Defendants acquired from it by means of any of the deceptive trade practices complained of herein.

G. That the State of Montana recover from Defendants the costs of this action, including reasonable attorneys' fees.

H. That the Court order such other and further relief as it may deem just, necessary and appropriate.

COUNT III

BREACH OF CONTRACT

CLAIM BROUGHT TO RECOUP STATE'S DAMAGES

132. The State of Montana incorporates by reference all preceding paragraphs as if fully set forth herein.

133. As required by 42 U.S.C. § 1396r-8, each Defendant entered into a Rebate Agreement with the Secretary of Health and Human Services ("DHHS"). In that agreement, each agreed to comply with Section 1396r-8, and hence:

(a) Agreed to report its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates where necessary; and

(b) Agreed that it would determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid;" and

(c) Agreed that the best price would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

134. The State of Montana was an intended third-party beneficiary of these contracts between the Defendants and the DHHS.

135. After execution of this agreement, each Defendant reported its average manufacturer's price in each quarter to the Medicaid Program.

136. In keeping with their artificial inflation of the AWPs, each Defendant did not report the actual "best price," for, but not limited to the drugs identified in ¶¶ 29 through 46 but instead excluded discounts and other inducements offered to physicians to increase use of a drug being sold at AWP.

137. Defendants have therefore breached their contracts with the DHHS, and caused massive damage to the State of Montana.

WHEREFORE, the State of Montana prays as follows:

A. That the Court adjudge and decree that Defendants have engaged in the conduct alleged herein.

B. That the Court order Defendants to pay damages to the State of Montana in an amount to be determined after trial.

C. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

COUNT IV

MEDICAID FRAUD

(Violations of § 53-6-160)

CLAIM FOR COST RECOVERY

138. The State of Montana incorporates by reference all preceding paragraphs as if fully set forth herein.

139. This Claim is brought for Medicaid cost recovery pursuant to Mont. Code Ann. §§ 53-6-160 and 53-6-143(4).

140. Each of the Defendant pharmaceutical companies is a manufacturer of drugs included in the Montana Medicaid drug formulary.

141. Pursuant to 42 U.S.C. § 1396r-8, each of the Defendant pharmaceutical companies entered into a rebate agreement with the Medicaid Program under which the Medicaid Program would receive rebates determined in part by "best price," which is defined as "the lowest price available from the manufacturer."

142. In particular, as part of the rebate agreement, each Defendant agreed that:

(a) It would determine its best price, taking into account discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and would make quarterly rebates where necessary to bring the price down to the actual lowest price offered to any commercial entity;

(b) It would also determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid;" and

(c) It would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of a product at a nominal price was not contingent on any other sale.

143. After execution of its agreement, each Defendant reported its "best price" in each quarter to the Medicaid Program.

144. In keeping with their artificial price inflation scheme, each Defendant with respect to, but not limited to the following drugs, did not report the actual "best price" or "average manufacturer's price," but instead (i) reported higher prices and (ii) excluded discounts and other inducements offered to physicians that resulted in lower prices than the prices reported to the Medicaid Program. The drugs include: Calcijex®, Methapred®, Ativan®, Premarin®, Epogen/Procrit®, Neupogen®, Aransep®, Zoladex®, Casdex®, Pentacarinat®, Depocyt®, Gammagard®, Blenoxane®, Taxol®, Albuterol®, Zovirax®, Alkeran®, Hycamtis®, Amikin®, Neosar®, Toposar®, Andrucil®, Camptosar®, Ellence®, Lasix®, Novantrone®, Nebcin®, Vancocin®, Oncovin®, Garamycin®, IntronA®, and Temodar®.

145. Each of the Defendants thereby violated Mont. Code Ann. § 53-6-160(1) in that they submitted untrue, incomplete, inaccurate, and misleading information used to determine the amount of payment under the Medicaid program. More specifically, each Defendant made or caused claims to be made to the effect that the Medicaid Program was receiving rebates based upon accurately reported "best price" information, knowing the claims to be rendered false, in whole or in part, by falsely reporting the prices paid by commercial entities for its products and not accounting for the discounts and other inducements offered to commercial entities. Further, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each Defendant made or caused to be made false statements promising that it would comply with the mandates of 42 U.S.C. § 1396r-8.

146. Defendants knew, or by virtue of their position, authority or responsibility should have known, of the falsity of the claim, statement or representation.

147. Defendants had the authority or responsibility to make such claims, statements and representations, exercised that authority and, as a direct or indirect result, the false statement was made, resulting in a claim for an item when Defendants knew or had reason to know that they were not entitled under applicable statutes, regulations, rules, or policies to Medicaid payment or for the amount of payment requested or claimed.

148. As a result of the Defendants' violations of § 53-6-160, the Medicaid Program paid substantially higher prices for Defendants' products than it could have, and the Medicaid Program was deprived of its appropriate rebate as a result of Defendants' inaccurate reporting of best price.

WHEREFORE, the State of Montana prays as follow:

A. That the Court adjudge and decree that the Defendants have engaged in the conduct alleged herein;

B. That the Court adjudge that the conduct is unlawful and in violation of § 53-6-160;

C. That, pursuant to § 53-6-143(4), the Court find each Defendant liable for an amount equal to the amount unlawfully obtained; and

D. That the Court order such other and further relief as it may deem just, necessary and appropriate.

COUNT V

FALSE CLAIMS

(Violations of § 17-8-231)

CLAIM FOR FORFEITURE, CIVIL PENALTIES, DOUBLE DAMAGES AND LEGAL COSTS

149. The State of Montana incorporates by reference all preceding paragraphs as if fully set forth herein.

150. This Claim is brought for forfeiture, civil penalties, double damages and legal costs pursuant to Mont. Code Ann. § 17-8-231.

151. Each of the Defendant pharmaceutical companies is a manufacturer of drugs included in the Montana Medicaid drug formulary.

152. Pursuant to 42 U.S.C. § 1396r-8, each of the Defendant pharmaceutical companies entered into a rebate agreement with the Medicaid Program under which the Medicaid Program would receive rebates determined in part by "best price," which is defined as "the lowest price available from the manufacturer."

153. In particular, as part of the rebate agreement, each Defendant agreed that:

(a) It would determine its best price, taking into account discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and would make quarterly rebates where necessary to bring the price down to the actual lowest price offered to any commercial entity;

(b) It would also determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid;" and

(c) It would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of a product at a nominal price was not contingent on any other sale.

154. After execution of its agreement, each Defendant reported its "best price" in each quarter to the Medicaid Program.

155. In keeping with their artificial price inflation scheme, each Defendant did not report the actual "best price" or "average manufacturer's price," but instead (i) reported higher prices and (ii) excluded discounts and other inducements offered to physicians that resulted in lower prices than the prices reported to the Medicaid Program.

156. Each of the Defendants thereby violated Mont. Code Ann. § 17-8-231, in that they submitted false, fictitious and fraudulent claims for payment to the State. More specifically,

each Defendant made or caused claims to be made to the effect that the Medicaid Program was receiving rebates based upon accurately reported "best price" information, knowing the claims to be rendered false, in whole or in part, by falsely reporting the prices paid by commercial entities for its products and not accounting for the discounts and other inducements offered to commercial entities. Further, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each Defendant made or caused to be made false statements promising that it would comply with the mandates of 42 U.S.C. § 1396r-8.

157. Defendants knew, or by virtue of their position, authority or responsibility should have known, of the falsity of the claims.

158. Defendants had the authority or responsibility to make such claims, statements and representations, exercised that authority and, as a direct or indirect result, the false statement was made, resulting in a claim for an item when Defendants knew or had reason to know that they were not entitled under applicable statutes, regulations, rules, or policies to Medicaid payment or for the amount of payment requested or claimed.

159. As a result of the Defendants' violations of § 17-8-231, the Medicaid Program paid substantially higher prices for Defendants' products than it could have, and the Medicaid Program was deprived of its appropriate rebate as a result of Defendants' inaccurate reporting of best price.

WHEREFORE, the State of Montana prays as follow:

A. That the Court adjudge and decree that the Defendants have engaged in the conduct alleged herein;

B. That the Court adjudge that the conduct is unlawful and in violation of § 17-8-231;

C. That, pursuant to § 17-8-231, the Court order that each Defendant forfeit the entirety of their claims and pay (i) civil penalties of $2,000 per false claim, (ii) double the

damages sustained by the State as a result of the false claim, and (iii) the State's legal costs incurred in connection with this action; and

D. That the Court order such other and further relief as it may deem just, necessary and appropriate.

COUNT VI

PUNITIVE DAMAGES

CLAIM BROUGHT ON BEHALF OF THE STATE OF MONTANA

160. The State of Montana realleges and incorporates the previous paragraphs of this Complaint as though fully set forth herein.

161. As detailed in this Complaint, Defendants have engaged in actual fraud and have acted with actual malice.

(a) Defendants have made false representations with knowledge of their falsity, have concealed material facts with the purpose of depriving the State of Medicaid monies, and the State has rightfully relied upon such misrepresentations and injury has resulted as a result of such reliance.

(b) Defendants also had knowledge of facts or intentionally disregarded facts that created a high probability of injury to the State and Medicaid participants, and deliberately proceeded to act in conscious or intentional disregard of, or with indifference to, the high probability of this injury.

WHEREFORE, the State of Montana prays as follows:

A. That the Court adjudge and decree that Defendants have engaged in the conduct alleged herein.

B. That the Court order Defendants to pay punitive damages to the State of Montana in an amount to be determined after trial.

C. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

DATED this _____ day of February, 2002.

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